Clinical Guidelines

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Did you know, …

- ~50% of current therapies have never been subjected to an RCT?
  - Williamson, Ann Int Med 1989
- RCT-tested therapy average 17 years to ‘routine’ use.
  - Nalor Lancet, 1995

Objectives

- Review definitions and processes
  - What is a guideline?
  - How is it developed? Who developed it?
  - Can you trust the guideline?
  - Is it something you should implement in your facility/practice?
- Provide resources
- Discuss problems

Lecture Outline

1. Guideline Development
2. Guideline Analysis
3. Guideline Implementation
4. Guideline Resources

Why Guidelines?

1. Make EBHC standards explicit and accessible
2. Aid decision making in clinic and at the bedside (easier/more objective)
3. Yardstick for assessing professional performance
4. Educate patients/providers about “current best practice”
5. Improve cost effectiveness of healthcare systems
6. A tool for external control

Greenhalgh, 2001

Guidelines vs. Standards

- **Guidelines**: Recommendations for best practice
- **Standards**: Practices that are necessary and that any provider (under the given circumstances) would be expected to render

Drawbacks of Guidelines

1. Poorly grounded in ‘evidence’
2. Standardize to ‘average’ practice rather than ‘best’ practice
3. Inhibit innovation
4. Medicolegal implications?
5. National guidelines may not reflect local needs
6. Balance of power/Politics

Points to Consider

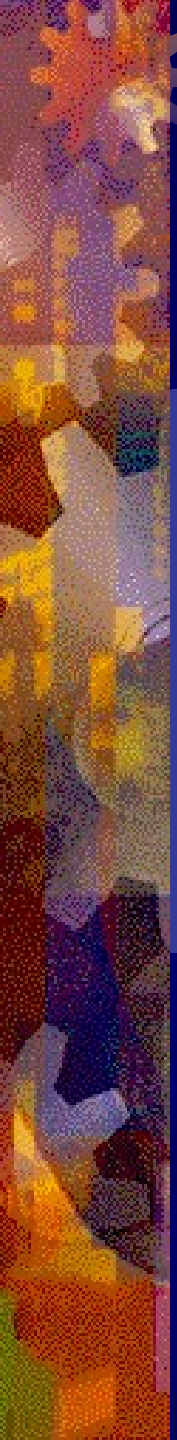
- Guidelines typically apply to general conditions, not particular circumstances
- They require an element of ***extrapolation***

More Points to Consider

- Following EBM guidelines may generally (but not always) improve care
- Deviating from EBM guidelines does not necessarily signal poor care
- In the UK, providers have a contractual obligation to provide care based on best available research evidence

What Makes a “Good Guideline”

- Easy to use and understand
- Provides genuine guidance
- Population clearly defined
- Based on evidence
- Flexible
- Measurable
- Implement-able for your facility
- Current



Guideline Development

Guideline Development

1. No clear process
2. Consensus Methodology
3. EBM (non-systematic)
4. EBM (systematic)

Guideline Development #1

- No Clear Process
  - Less and less common
  - No outline of development process
  - Historically position statements from specialty groups
    - e.g ACSM Position Statements

Guideline Development #2

- Consensus Methodology
  - “BOGSAT”
  - Expert opinion
  - Relatively common
  - Typically have relatively little focus on cost or ‘healthcare systems outcomes’
    - e.g. NIH Consensus Conferences

Guideline Development #3

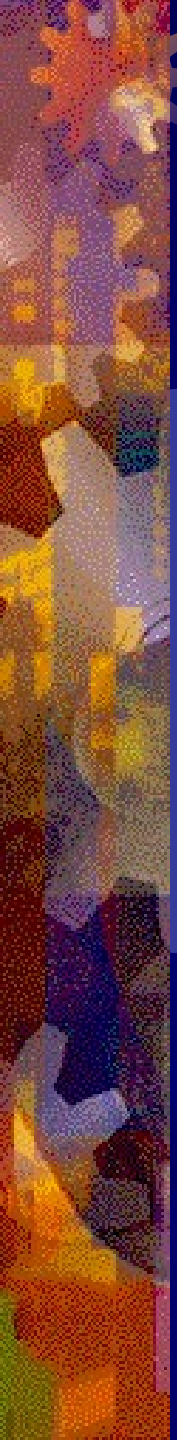
- Evidence-based without extrapolation
  - Use systematic analysis of evidence
  - Fail to examine impact on population-based outcomes
    - e.g. AHCPR guidelines

Guideline Development #4

- Explicit evidence-based methodology
  - Systematic analysis of evidence
  - Projects impact of guideline implementation on health status, patient/clinician satisfaction, cost, utilization, etc.

Guideline Development

- Most guidelines, therefore, truly represent an amalgam of
  - Clinical experience
  - Expert opinion
  - Research



Guideline Analysis

Guideline Components

1. Evidence Summary
   - Validity
   - Reliability
2. Detailed Instructions on use
   - Applicability
   - Ease of use

Evidence Summary

1. Comprehensive literature review
2. Is level of evidence described and defined
   - Multiple taxonomies (>100)

Not an easy task. Involves time, knowledge and resources. As with systematic review—best left to someone else!

Guideline Evaluation

- Analogous to processes from yesterday for therapy/diagnosis/review articles

- 2 resources
  - Group Health Guideline Evaluation Tool
  - National Health Services Guideline Evaluation Tool

If valid, before implemen

Guideline Evaluation—4 B's

1. Is the burden of illness sufficient in your community to warrant implementation?

Sackett, 2000

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Consensus guideline on subclinical thyroid disease

Clinical question
What diagnostic methods and treatments are useful for managing subclinical thyroid disease?

Bottom line
There is insufficient evidence to support the treatment of subclinical thyroid disease (thyroid-stimulating hormone [TSH] level = 0.1 - 0.45 mIU/L or 4.5 - 10.0 mIU/L). Case finding and treatment is more likely beneficial in pregnant women and women older than 60 years. (LOE = 2a)

Reference
Surks MI, Ortiz E, Daniels GH, et al. Subclinical thyroid disease: Scientific review and guidelines for diagnosis and management. JAMA 2004; 291:228-38.

Study design: Systematic review

Setting: Various (guideline)

Synopsis
Subclinical thyroid disease is generally defined as a TSH level either minimally above or below the normal reference range in a patient with few or no definitive clinical signs or symptoms of thyroid dysfunction. To determine the most appropriate work-up and treatment of these patients a consensus panel of experts reviewed 195 papers identified from multiple sources, including MEDLINE, the Agency for Healthcare Research and Quality, the Cochrane Controlled Trials Register, the National Health Services (UK) database, among others. Evidence supporting the progression of subclinical to overt hypothyroidism was rated as good, but there was insufficient evidence to conclude that treatment prevents progression. Serum TSH levels greater than 10 mIU/L were related to elevated serum cholesterol but evidence supporting the benefit of treatment was again minimal. All other associations of symptoms and benefits of treatment for subclinical hypothyroidism were unsupported by the available evidence. Evidence relating a low TSH level (< 0.1 mIU/L) to an increased risk of atrial fibrillation and overt hyperthyroidism was rated as good, but there was insufficient evidence to support treatment to prevent these outcomes. Maintaining the TSH within the reference range did improve bone mineral density, but there was no evidence supporting a reduction in clinically significant fractures. All other associations of symptoms and benefits of treatment for subclinical hyperthyroidism were unsupported by the available evidence. There is good evidence to justify case-finding and treatment of subclinical hypothyroid disease in pregnancy.

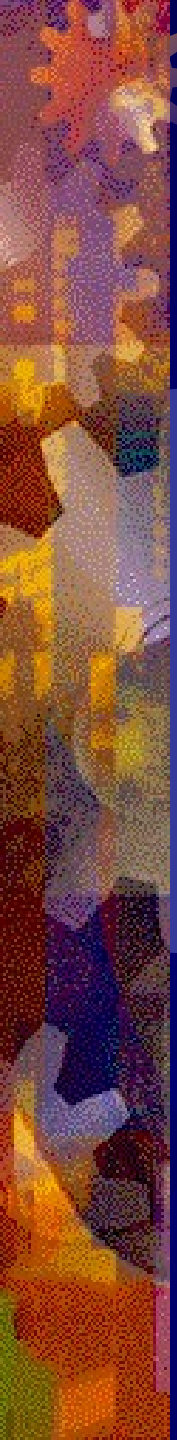
Internet

Guideline Implementation B-2

2. Beliefs-Are the beliefs of the patients/providers compatible with successful guideline implementation?
3. Bargain-Is it cost-effective?
4. Barriers-What barriers exist for implementation? Is it worth overcoming them?

In a Nutshell

1. Is guideline development process described? (recall 4 types)
2. Who developed the guidelines?
3. Why were the guidelines developed?
4. What is the strength of the evidence?
5. Does the guideline possess the attributes of a “good guideline”?
6. Has the guideline been piloted?



Guideline Implementation

Why Bother?

- Improve Health Outcomes
- Decrease Inappropriate Practice Variation
- Improve Health Care Process
- Optimization of Resources

The Fundamental Provider Gap

- Are Clinical Practice Guidelines:
  - Advice/support for clinicians and clinical decision making?
  - Prescriptive legal standards?

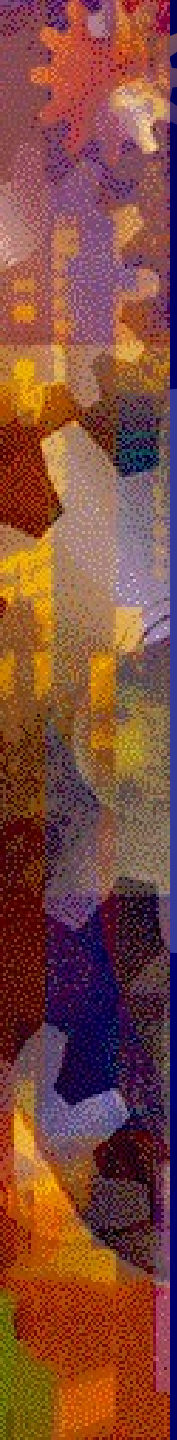
Trust the Force Luke

- Recommended by professional association
- Known to improve patient care
- Part of regular routine
- Reminders at point of care
- Past experience with guidelines

PRO

- Value right to independent decision making
- Not convinced about outcomes
- Not part of routine
- Ignore reminders
- Past experience

CON



Barriers to Provider Adherence...

Cabana, JAMA 1999

Lack of Awareness

- Most providers unaware of most guidelines
  - Given the volume and variant quality of available guidelines, many providers are unaware of what's already out there.

Lack of Familiarity

- While providers may be aware of the guideline, they still are often unfamiliar with its design and/or how to implement the guideline

Lack of Agreement

- Physicians often disagree with the recommendations of the guideline and/or the concept of guidelines in general

Some Good News

- Pneumococcal vaccine 26%-81%
- Influenza vaccine 28%-78%
- Annual A1C 59%-94%
  - Influence of CPG within the VA healthcare system

More data from the VA

- Clinicians who actually read the guidelines found them helpful
  - Only 40% of respondents actually read the guidelines (DM/Asthma/IHD/Depression)
- 60% felt CPG valid and applicable to their patients (non-systematic)
- Half felt that CPG were either too long or too short

Barriers to Implementation VA Study February 2004

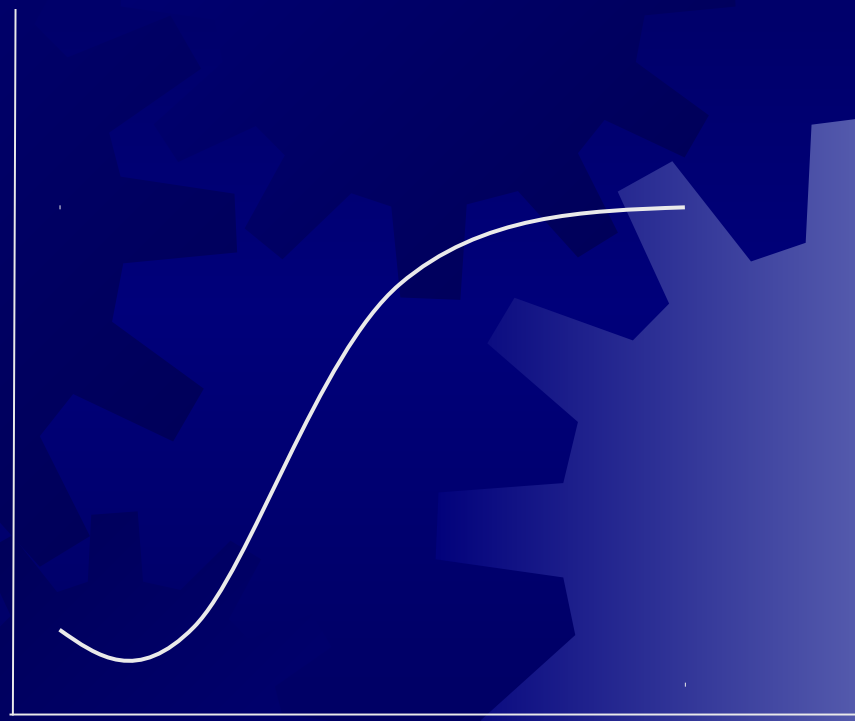
- Time
- Resources
- Accessibility/Ease of Use
- Lack of knowledge
- Patient disinterest
- Opposition to “cookbook” approach

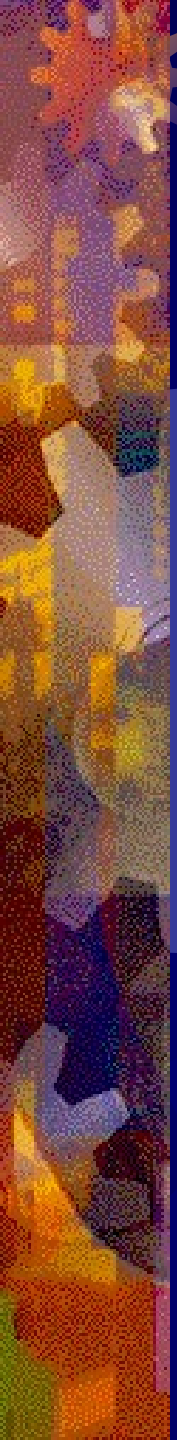
Guideline Implementation

- The most effective guidelines are:
  - Developed/adapted locally by the people who will use the guidelines
  - Introduced as part of a specific educational intervention
  - Implemented with specific prompts and tools available at the point-of-care

Social Cognition Models

- Innovators 3%
- Early Adopters 14%
- Early Majority 34%
- Late Majority 34%
- Laggards 16%





Shopping for Guidelines

Guideline Resources

- National Guidelines Clearinghouse
  - www.guidelines.gov
    - Repository of hundreds of guidelines sponsored by AHRQ, DHHS and AMA
    - Provides summary recommendation, evidence source and identifying information

NGC - National Guideline Clearinghouse - Microsoft Internet Explorer provided by USNH Sigonella

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National Guideline Clearinghouse

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Welcome!

You are connected to the National Guideline Clearinghouse™ (NGC™), a public resource for evidence-based clinical practice guidelines. NGC is sponsored by the Agency for Healthcare Research and Quality (AHRQ), U.S. Department of Health and Human Services, in partnership with the American Medical Association and the American Association of Health Plans-Health Insurance Association of America. Click on About NGC to learn more about us.

Start your search by typing keywords into the search box on this page, or use the NGC Browse or Detailed Search features.

NGC News

New Centers for Disease Control and Prevention (CDC) recommendations on the use of pneumococcal conjugate vaccine.

New/updated AAFP, CDC, Smith & Nephew, USPSTF, Work Loss Data Inst, and Wound Ostomy Nurses guidelines. Go to "What's New This Week".

Look for practical, ready-to-use tools for measuring and improving the quality of Americans' health care in the Agency for Healthcare Research and Quality's (AHRQ's) QualityTools Web site.

Look for Quality Measures in AHRQ's National Quality Measures Clearinghouse (NQMC).

Subscribe to the NGC Weekly E-mail Update Service.

http://www.ahrq.gov/ Internet

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Guideline Resources

- VA Guidelines
  - http://www.oqp.med.va.gov/cpg/cpg.htm

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CPG Home

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Clinical Practice Guidelines

Office of Quality and Performance

OQP < CPG

CARDIOVASCULAR

- Chronic Heart Failure (CHF)
- Hypertension (HTN)
- Ischemic Heart Disease (IHD)
- Dyslipidemia (LIPIDS)

ENDOCRINE

- Diabetes Mellitus (DM)

EYE

- Glaucoma

GENITOURINARY TRACT

- Benign Prostate Hyperplasia (BPH)
- Dysuria
- Erectile Dysfunction (ED)
- Pre-End-Stage Renal Disease (ESRD)

MENTAL HEALTH

- Major Depressive Disorder (MDD)
- Psychoses (PSYCH)
- Substance Use Disorder (SUD)

MUSCULOSKELETAL

- Low Back Pain (LBP)

What's New!

Stroke Rehabilitation(STR)

Uncomplicated Pregnancy (UP)

OPIOID Therapy for Chronic Pain

Terrorism Pocket Guide - Non VA Ordering Information

SUD:Self Help Organizations for alcohol and drug problems (See Guideline Community - Related Resources within Substance Use Disorder)

Biological, Chemical, and Radiation Induced Illnesses: Centers for Disease Control and Prevention (CDC) guidelines for:
1) performing single-platform absolute CD4+ T-Cell determinations with CD45 Gating for persons infected with human immunodeficiency virus.
2) Smallpox vaccination and adverse reactions. Guidance for clinicians.

Biological, Chemical, and Radiation Induced Illnesses: Center for Civilian Biodefense Strategies, School of Medicine, Johns Hopkins University guidelines for:
(1) Botulinum toxin as a biological weapon: medical and public health management and (2) Botulinum toxin as a biological weapon. (Addendum);
(1) Smallpox as a biological weapon: medical and public health management. (2) Smallpox as a biological weapon. (Addendum).

Protect Yourself: Prepare for emergencies and disasters;protect yourself by learning about chemical, biological weapons ...

Clinical Practice Guidelines

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- Institute for Clinical Systems Improvement
  - http://www.icsi.org/index.asp

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Institute for Clinical Systems Improvement

The Institute for Clinical Systems Improvement (ICSI), a collaboration of health care organizations, is an objective voice dedicated to championing health care quality and to helping its members identify and accelerate the implementation of best clinical practices for their patients. Learn more about ICSI.

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03/22/04
Clinical Evidence Roundtable: Breast Cancer Screening

05/13/04 - 05/14/04
Colloquium on Clinical Quality Improvement

see more events »

Recent News:

New and Recently Updated Technology Assessment Reports

New and Recently Revised Guidelines

"Harvesting Innovation: Better Patient Care Through Creative Redesign" theme of 2004 Colloquium May 13-14

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Healthcare Guidelines GO

Pneumonia, Community-Acquired

Download: Community-Acquired Pneumonia (818 KB)

Released 12/2003

Scope and Target Population:

To provide recommendations for the diagnosis and treatment of community-acquired pneumonia in patients 16 years of age and older. This document also provides recommendations for outpatient management and indications for hospitalization, taking into consideration ongoing changes in antibiotic resistance. This guideline excludes patients with pneumonia acquired in nursing homes or other institutions, aspiration pneumonia, HIV infection and pneumonia in immunocompromised patients.

Clinical Highlights and Reommendations:

1. Triage guidelines to identify patients with lower respiratory infections are provided in this guideline. Patients with two or more of the specified signs/symptoms should be given an urgent provider visit to establish a diagnosis of pneumonia or other serious lower respiratory tract infection.

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- AHRQ
  - http://www.ahcpr.gov/clinic/cpgsix.htm

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Treating Tobacco Use and Dependence

Pathfinder page links to materials that help tobacco users quit.

National Guideline Clearinghouse™

National Guideline Clearinghouse™: Fact Sheet

Invitation to Submit Guidelines to the National Guideline Clearinghouse™

Clinical Practice Guidelines Online

A series of 19 Clinical Practice Guidelines was developed with the support of the former Agency for Health Care Policy and Research and released over a 4-year period, 1992-1996.

Tobacco Cessation

U.S. Public Health Service Guideline

Treating Tobacco Use and Dependence: Online Continuing Medical Education Course

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- The Golden Hour
  - http://www.goldenhour.co.il/

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Clinical practice guidelines

last update: 01/02/04

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- The Scottish Intercollegiate Guidelines Network (SIGN): ******- fantastic
- eGuidelines -The Best Guidelines in Practice ****** new!!! (free registration is needed)
- PRODIGY Guidance******
- Australian- Clinical Guidelines ****** new!!!
- Canadian Clinical Guidelines ******
- ACP Guidelines Web site ******
- Medical Guidelines by Specialty -1******
- Medical Guidelines by Specialty -2******
- Cancer Care - Clinical Practice Guidelines ******
- U.S. Preventive Services Task Force - Clinical Preventive Guidelines ******

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Guidelines Resources

- Colorado Clinical Guidelines Cooperative
  - http://www.coloradoguidelines.org/guidelines.html

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Colorado Clinical Guidelines Collaborative

Improving Healthcare through evidence-based guidelines and systems

CCGC Guidelines

This page offers links to all of our guidelines and their supporting material. All items are freely available for download and distribution.

Please note: *no changes may be made to any of the CCGC materials.*
If you have questions about the content of any of the guideline documents, please contact the CCGC office.

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Materials by Disease-state

Disease-State	Updated
Asthma	April 2002
Antibiotics in UR Infections	November 2000
Colorectal Cancer Screening	April 2003 NEW
Depression	May 2003 NEW
Diabetes in Adult Patients	May 2003 NEW

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Guidelines Resources

- Canadian Medical Association
  - http://mdm.ca/cpgsnew/cpgs/index.asp

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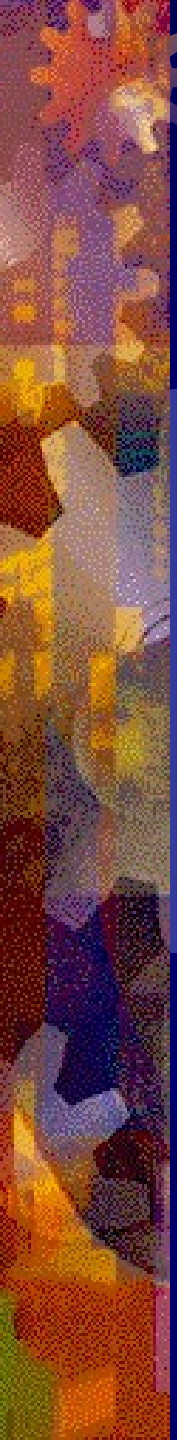

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- Effective Treatment Options for Patients with COPD (POEM)
- Asthma Education Reduces Readmission Rate (POEM)
- One-Day Drug Regimen Eliminates *H. pylori* (POEM)
- Hypothyroidism Common in Patients Infected with HIV
- Donepezil Delays Nursing Home Placement
- Use of Drug-Coated Stents Cuts Restenosis Rates
- Preventing Sudden Cardiac Death in Diabetic Patients
- Should Patients with VTE Be Tested for Thrombophilia?
- MRI to Detect Bone Erosions in Rheumatoid Arthritis
- Fibrinolysis or Angioplasty in Acute Myocardial Infarction
- Acetylcysteine Prophylaxis for Radiocontrast Nephropathy
- Diagnosis and Treatment of Early Alzheimer's Disease

Children's Health

- Serotonergic Antidepressants in Children and Adolescents
- Low-Nutrient-Density Food Consumption by Children
- New Pneumococcal Vaccine in High-Risk Children
- What Are the Indications for Surgery for Glue Ear?

Women's Health

- Can Biophysical Profiles in Labor Predict C-Section?
- Effect of Oral Contraceptives on Functional Ovarian Cysts
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- Metabolic Abnormalities in Bulimia Nervosa
- Transdermal Estrogen and Venous Thromboembolism
- Breast Cancer Risk Related to Type of Hormone Therapy

Mental Health

- Depression After Coronary Artery Bypass Surgery
- Suicide Risk During Lithium and Divalproex Therapy

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